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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/731,554 | 12/09/2003 | David H. Walker | D6152CIP2/D/D1 | 6350 |
| 7590 01/11/2006 | | | | |
| David L. Parker FULBRIGHT & JAWORSKI L.L.P 600 Congress Avenue, Suite 2400 Austin, TX 78701 | | | EXAMINER BASKAR, PADMAVATHI | |
| | | | ART UNIT 1645 | PAPER NUMBER |

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,554

Applicant(s)

WALKER ET AL.

Examiner

Padmavathi v. Baskar

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/28/05&3/15/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response to restriction and amendment filed on 8/13/05 is acknowledged.

Status of claims

2. Claims 1-20 have been canceled.

New Claims 21-23 have been added and are under investigation.

Priority

3. This application 10/731,554 claims priority under 35 U.S.C. 120 to 09/811,007, 03/16/2001 U.S.PAT 6,660,269 which is a DIV of 09/660,587 09/12/2000 U.S.PAT 6,392,023 which is a CIP of 09/261,358 03/03/1999 U.S.PAT 6,403,780 which is a CIP of 09/201,458 11/30/1998 U.S. PAT 6,458,942.

Information Disclosure Statement

4. Information Disclosure Statements (IDS) filed on 1/28/05 and 3/15/04 are considered and a signed copy of each is attached to this Office action.

Drawings

5. The drawings filed on 12/09/03 are accepted by the examiner.

Specification Informalities and objection

6. Applicant is advised to update the status of all priority applications whether pending or patented.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his/her invention

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8. Claims 21-23 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-23 are rejected as being vague for the recitation “---SEQ ID N0: 46---” because the polypeptide is identified by a sequence identification number (SEQ.ID.NO). Therefore, Does applicant intend to mean a method of inhibiting *Ehrlichia canis* infection in a subject comprising the steps of: identifying a subject infected with *Ehrlichia canis*; and administering a composition comprising the isolated polypeptide, SEQ ID N0: 46 and a pharmaceutically acceptable carrier?

Claim 21 is also rejected as being vague for the recitation of “of inhibiting *Ehrlichia canis* infection in a subject ---- prior to exposure or suspected of being exposed to”. It is not clear how to inhibit *E.canis* infection in a subject prior to exposure or suspected of being exposed to an infection since there is no *E.canis* infection to start with. Does applicant intend to mean a method of preventing or inhibiting *Ehrlichia canis* infection----?

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohashi et al 1998 (see IDS # C24 3/15/04, Infec.Immun, 66; 132-139) in view of Ohashi et al 1998 (see IDS # C23, 3/15/04, J.Clin. Microbiol, 2671-2680).

Claims are drawn to a method of inhibiting *E.canis* infection in a subject comprising administering a composition comprising SEQ.ID.NO: 46 in a pharmaceutically acceptable carrier.

Ohashi et al 1998 C24 teach *E.chaffeensis* and *E. canis* outermembrane proteins ranging from 23 to 30kD are major immunodominant proteins (see figure 2 A and 2B). The recombinant protein p28 of *E.chaffeensis* was used to raise antibody in Rabbits. The antibody and serum from patient infected with *E.chaffeensis* reacted with the recombinant proteins 29, 28 and 25kD proteins of *E.chaffeensis*, and a 30kDprotein of *E.canis*. Further, the prior art teaches a method of inhibiting *E.chaffeensis* infection by administering immunodominant major outer membrane proteins 28 - 30KD of (see abstract and figure 9) *E.chaffeensis*. Mice immunized with recombinant p28 protein were protected from infection with *E.chaffeensis* (see page 137, left column first and second paragraphs). Thus the prior art teaches a method of inhibiting *E. chaffeensis* infection using 28-30 KD antigens of *E. chaffeensis* in a pharmaceutically acceptable carrier. However, the prior art does not teach a method of inhibiting *E. canis* infection using SEQ.ID.NO: 46. Ohashi et al. J.Clin. Microbiol, 1998 C23 teach immunodominant major outer membrane protein 30KD of *E.canis* (see abstract and figure 1). Further, the prior art teaches the serum from mice immunized with recombinant rP30 protein and the sera obtained from infected patients were reactive to rP30 antigen and 30kD protein from *E.canis* (see figure 1). The disclosed prior art protein, rP30 is 100% identical (see

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database Uniprot_05, Accession number Q9ADV2_EHRCA) with one conservative amino acid substitution, see enclosed sequence alignment) with the claimed SEQ.ID.NO: 46. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to administer readily available rP30 protein, SEQ.ID.NO: 46 from *E.canis* instead of p28 from *E.chaffeensis* in a method to inhibit *E. canis* infection with a reasonable expectation of success because Ohasi et al 1998 (C24) teach a method of inhibiting Ehrlichia infection in mice by administering p28 protein from *E.chaffeensis* and mice immunized with recombinant p28 protein were protected from infection with *E.chaffeensis*. An artisan of ordinary skills would have been motivated in applying the art disclosed by Ohasi (C24) et al to inhibit *E.canis* infection instead of *E.chaffeensis* in a subject by administering SEQ.ID.NO: 46 of *E.canis* in a pharmaceutically acceptable carrier because the prior art C24 not only teaches that mice were protected against *E.chaffeensis* infection (C24) by administering an immunodominant major outer membrane proteins 28 - 30KD of (see abstract and figure 9) *E.chaffeensis* but also clearly suggests the major outer membrane proteins 28-30kD are immunodominant and cross-reactive between *E.chaffeensis*, and *E.canis* (see page 132, left column, second paragraph) and C23 teaches 30KD of *E.canis* is an immunodominant major outer membrane protein. Therefore, the claimed invention is prima facie obvious over Ohashi et al 1998 (C24) in view of Ohashi et al 1998 (C23) absent any convincing evidence to the contrary.

Status of claims

11. No claims are allowed.

Conclusion

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile

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must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989.

The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



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